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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,858	08/18/2003	Katherine M. Aldred		3669

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EXAMINER	
GEORGE, KONATA M	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/642,858	ALDRED, KATHERINE M.	
	Examiner	Art Unit	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *11-20* is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are pending in this application.

Action Summary

1. The rejection of claims 1-10 under 35 U.S.C. 103(a) over Chandrasekaran (4,286,592) in view of Tawashi (5,648,101) is being maintained for the reasons stated in the previous office action.

2. The rejection of claims 11-20 under 35 U.S.C. 103(a) over Chandrasekaran (4,286,592) in view of Tawashi (5,648,101) is hereby withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandrasekaran (US 4,286,592) in view of Tawashi (US 5,648,101).

Applicants' claims a transdermal patch comprising a drug reservoir layer, a rate-controlling membrane secured to the reservoir layer and a contact adhesive and the reservoir contains a hematinic substance.

Determination of the scope and content of the prior art

(MPEP §2141.01)

Figure 1 of Chandrasekaran discloses a transdermal device comprising a backing layer, a drug reservoir layer composed of a drug dispersed in a carrier, a contact adhesive layer and a release liner layer (col. 2, lines 54-60). The backing layer can comprise an aluminized polyester film and the coating layer comprising siliconized polyester (example 1, col. 4, lines 38-39, 47-48 and example 2, col. 5, lines 15-16, 22-23). The drug reservoir can comprise silicone-based carriers or carriers made from mixtures of mineral oil and polyisobutenes (col. 3, lines 35-36). It is taught by example 1 that the transdermal delivery device is at least 0.1 mm thick.

Tawashi teaches in example 9, column 10, lines 11-19, a transdermal patch comprising a cellulose matrix impregnated with a ferrous sulfate solution.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

The prior art reference of Chandrasekaran does not teach the hematinic substance as described in claims 2 and 14 or using the device to treat iron deficiency.

Finding of prima facie obviousness

***Rational and Motivation* (MPEP §2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Tawashi in the transdermal patch of Chandrasekaran. Chandrasekaran is silent with respect to the preferred drug; therefore, it is the position of the examiner that any drug can be employed in the invention. Tawashi is being replied upon to teach the ferrous sulfate can be formulated into a transdermal patch. The expected result of combining the teachings would be transdermal device comprising drug reservoir layer, a rate-controlling membrane secured to the reservoir layer and a contact adhesive and a hematinic substance such as ferrous sulfate. Using the device to treat iron deficiency would have been obvious to one of ordinary skill in the art as it is common practice to use ferrous sulfate as a treatment of iron deficiencies.

Response to Arguments

4. Applicant's arguments filed November 14, 2006 have been fully considered but they are not persuasive.

Applicants argue that the prior art reference of Chandrasekaran does not have a rate-controlling membrane. The examiner disagrees. Column 3, lines 40-42 of Chandrasekaran teaches that the contact adhesive layer plays a principal role in controlling the rate at which the drug is released. This statement implies that the contact adhesive has a dual purpose 1) as a rate-controlling layer and 2) as a contact adhesive. The applicant argues that the prior art reference of Tawashi does not teach using the hematinic substance to treat iron deficiency. The claims are directed towards a transdermal patch, not to a method of treating. "Treatment of iron deficiency" is intended use language. A statement of intended use is of little patentable weight unless it specifically alters one or more ingredients of said composition. In re Madder et al. 143 USPQ 248. Applicant argues that one of ordinary skill would not be motivated to use the teachings of Tawashi in the transdermal patch of Chandrasekaran. The examiner disagrees. Although the drug reservoir layer of Chandrasekaran does not teach a specific drug, it can be implied that any and all drugs could be use in the reservoir including hematinic substances.

Conclusion

5. Claims 1-10 are rejected.

6. Claims 11-20 are allowed. The prior art does not teach a method of treating iron deficiency comprising providing a drug reservoir layer containing a hematinic substance secured to the skin surface.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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